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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,678	09/02/2005	Hesson Chung	4698-0111PUS1	9260
2292 7590 03/20/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER KANTAMNINI, SHOUBHA				
ART UNIT 1617		PAPER NUMBER		
NOTIFICATION DATE 03/20/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/521,678

Applicant(s)

CHUNG ET AL.

Examiner

Shobha Kantamneni

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date 01/18/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

This application was filed on 09/02/2005, and is a national stage entry of PCT/KR03/01441 filed on 07/21/2003.

Claims 1-11 are pending, and examined herein on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 contain the abbreviation or trademark/trade name FK506. Where a trademark or trade or abbreviation name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirement of 35 U.S.C. 112, second paragraph. See *Exparte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the abbreviation or trademark or trade name cannot be used properly to identify any particular material or product. A abbreviation or trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a abbreviation or trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the

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abbreviation trademark/trade name or abbreviation is used to identify/describe particular agent, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Villa et al. (WO 00/76478, PTO-892).

Villa et al. discloses instant compound octylonium bromide. Villa et al. discloses controlled release oral pharmaceutical compositions containing an active ingredient such as octylonium bromide. See page 4, lines 21-32; page 5, line 24-page 6; page 8, lines 28-30; page 9, line 24. A composition comprising 20 g of octylonium bromide, and 550 g of 5-aminosalicylic acid is disclosed. See page 11, EXAMPLE 1. Process for making the controlled sustained release tablets containing octylonium bromide is also taught. See pages 5-8; page 11

Regarding, the limitations drawn to the intended use of the instant p-glycoprotein inhibitor, octylonium bromide has not been given any patentable weight i.e "to increase the absorption of drugs" as in claims 1, 9-10, "that can be administered with other drugs simultaneously" as in claims 5, 11, "that can be

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administered 5-60 minutes before administering other drugs" as in claim 6 because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963).

The recitations, "wherein octylonium bromide is formulated to sustain the release of octylonium bromide up to 12 hours", and "wherein the slow release formula is formulated.....control the release rate of the drug" as in instant claims 3, and 4, are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 ("Fed. Cir. 1985). See MPEP 21 13.

Thus, Villa et al. anticipates instant claims 1-11.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-6, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Casini et al. (US 4,978,772, PTO-1449).

Casini et al. discloses a pharmaceutical formulation containing octylonium bromide. See column 1, lines 9-21. The compositions therein contain octylonium bromide in an amount of 10-300 mg. See column 2, lines 40-49.

Regarding, the limitations drawn to the intended use of the instant p-glycoprotein inhibitor, octylonium bromide has not been given any patentable weight i.e "to increase the absorption of drugs" as in claims 1, 9-10, "that can be administered with other drugs simultaneously" as in claims 5, 11 "that can be administered 5-60 minutes before administering other drugs" as in claim 6 because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963).

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Thus, Casini et al. anticipates instant claims 1-2, 5-6, and 9-11.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-7, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Santicioli et al. (Nauyn-Schmiedeberg's Arch Pharmacol, 1999 359:420-427, PTO-1449).

Santicioli et al. discloses that octylonium bromide is used for the treatment of hypermotility and hypersensitivity disorders of the intestine. Santicioli et al. discloses oral administration of octylonium bromide. See page 420, right hand bottom paragraph; page 426, right hand bottom paragraph.

Regarding, the limitations drawn to the intended use of the instant p-glycoprotein inhibitor, octylonium bromide has not been given any patentable weight i.e "to increase the absorption of drugs" as in claims 1, 9-10, "that can be administered with other drugs simultaneously" as in claims 5, 11 "that can be administered 5-60 minutes before administering other drugs" as in claim 6 because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

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patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963).

Thus, Santicioli et al. anticipates instant claims 1, 5-7, and 9-11.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 7.30 am-3.30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D

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Patent Examiner

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/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617